

Attachment IV– Fixation Findings

Table 1. Fixation Findings Related to Nonunion Fractures Treated with Capacitive Coupling Non-invasive Bone Growth Stimulators

Reference	Stimulation Type	Number of Subjects with Fixation (%)	Type of Fixation Used	Impact of Fixation on Effectiveness
Abeed et al., 1998	Capacitive Coupling	Internal Fixation: 7/16 (43.8) External Fixation: 1/16 (6.3)	8/16 had metallic devices: <ul style="list-style-type: none"> • T-plate: 1 • L-plate: 1 • Tension Band Wire: 1 • Deep Compression Plate: 3 • Intramedullary Nail: 1 • External fixator: 1 	4/8 with metallic devices healed versus 5/8 without metallic devices healed. “Healing was not affected significantly by any of the following factors: whether or not the nonunion had been treated surgically prior to stimulation... or by the presence or absence of metal at the fracture site from previous surgery.”
Benazzo et al., 1995	Capacitive Coupling	0/21	Not applicable	Not reported
Brighton and Pollack, 1985	Capacitive Coupling	15/22 (68.2) nonunions	Multiple surgeries performed/nonunion (see p.0194 of petition) Materials include: pins in plaster, plate and screws, Intramedullary rod, screw fixation, Steinmann pin, cancellous screws, Hoffman apparatus, and hip screw (all of which involved a combination of debridement and/or bone grafting)	“The results in this small series were not affected by the non-union being recalcitrant...or by the presence of remaining metallic internal-fixation devices in the bone.”
Brighton et al., 1995	Capacitive Coupling	88/271 (32.5) 53/167 (31.7) treated with DC 14/56 (25) treated with CC 21/48 (43.8) treated with graft	“Metal in the form of a plate and screws or an intramedullary rod was present in 1/3 of the nonunions”	“In preliminary models, additional variables that were insignificant were gender ($p=0.84^*$), age ($p=0.75^*$), presence of metal ($p=0.59^*$), middle location (versus proximal)($p=0.41^*$) and distal location (versus proximal) ($p=0.39^*$).”

Table 1. Fixation Findings Related to Nonunion Fractures Treated with Capacitive Coupling Non-invasive Bone Growth Stimulators (Continued)

Reference	Stimulation Type	Number of Subjects with Fixation (%)	Type of Fixation Used	Impact of Fixation on Effectiveness
Scott and King, 1994	Capacitive Coupling	Active: 3/10 nonunions Placebo: 4/11 nonunions	Active: <ul style="list-style-type: none"> Küntscher nail: 1 Intramedullary nail: 1 Interfragmentary Screw: 1 Placebo: <ul style="list-style-type: none"> Screws: 3 Broken plate & Screws: 1 	Active: 2/3 healed Placebo: 0/4 healed

Table 2. Fixation Findings Related to Nonunion Fractures of the Tibia Treated with PEMF Non-invasive Bone Growth Stimulators

Reference	Stimulation Type	Number of Subjects with Fixation (%)	Type of Fixation Used	Impact of Fixation on Effectiveness
Bassett, 1981	Pulsed Electromagnetic Fields (PEMF)	Not Reported (NR)/125 22/125 (17.6) patients had prior surgical failures, with internal or external fixation given as an example.	NR	"The success rate was not materially affected by the age or sex of the patient, the length of prior disability, the number of previous failed operations, or the presence of infection or metal fixation."
Caullay and Mann, 1982	PEMF	1/4 (25) treated with internal fixation	8-screw steel plate	1/1 healed
Gossling et al., 1992	PEMF	521/1718 (30.3) active subjects	Cross-studies analysis (see p.0269 of petition) Examples of materials include: external/internal fixation, Küntscher nail, plate & graft, Lotte's nail, Phemister graft, plate, intramedullary nail, etc.	Range of healing across studies 78-100% The number of the surgeries impacts the effectiveness, not immobilization, although the quality of the procedure does matter.
Ito and Shirai, 2001	PEMF	18/30 (60) had the "presence of surgical hardware"	NR	14/18 (77.8%) united "The healing rate did no correlate with patient age or gender, the presence of surgical hardware, ..."
Meskens et al., 1988	PEMF	NR/57	NR	"The success rate was not significantly affected by disability time, the number of previous failed interventions or the presence of infection."
Sharrard, 1990	PEMF	5/45 (11.1) Treatment by internal or external fixation was an exclusion for the study	Stabilizing pins in the calcaneus and upper end of the tibia: 2 Internal or external fixation: 3	NR

Table 3. Fixation Findings Related to Nonunion Fractures of the Long Bones and Others Treated with PEMF Non-invasive Bone Growth Stimulators

Reference	Stimulation Type	Number of Subjects with Fixation (%)	Type of Fixation Used	Impact of Fixation on Effectiveness
Bassett et al., 1982	Pulsed Electromagnetic Fields (PEMF)	66/1078 (6.1) Number of patients who had PEMF + operative repair (otherwise NR)	Not Reported (NR)	<p>“...Combining PEMFs with effective immobilization and non-weightbearing during early phases of treatment, together with a graded rehabilitation program, the success rate in 53 ununited fractures of the tibial diaphysis was 92%.”</p> <p>“... Combining PEMFs with surgery (grafts) appears to offer an extremely high success rate.”</p>
Bassett et al., 1982	PEMF	NR/83 “No patient was included if internal or external fixation was used at the time of the graft, although some patients had metal devices in place from prior unsuccessful attempts to produce union.”	NR	<p>“...Not greatly different from those with bone-grafting alone (with or without internal fixation)...”</p>
Bassett et al., 1977	PEMF	1/26 (3.8)	Graft and rod	<p>“The one present limitation of this combined approach concerns internal fixation with metals. Large plates and intermedullary rods can modify field distribution and, thus far, no patients with large masses of metals have been included in the investigation.”</p>

Table 3. Fixation Findings Related to Nonunion Fractures of the Long Bones and Others Treated with PEMF Non-invasive Bone Growth Stimulators (Continued)

Reference	Stimulation Type	Number of Subjects with Fixation (%)	Type of Fixation Used	Impact of Fixation on Effectiveness
Bassett et al., 1978	Pulsed Electromagnetic Fields (PEMF)	Not Reported (NR)/220 “For a few patients with excessive motion (particularly in the humerus), external or internal skeletal fixation was applied prior to final coil positioning.”	NR (“various”)	“Internal metallic fixation was compatible with electromagnetic fields <i>if</i> the metals were nonmagnetic. This meant that most plates, rods and screws produced in the United States of America were satisfactory, since they were fabricated from 316L stainless steel or cobalt-chrome alloys. Pins in use with the Hoffmann apparatus were magnetic. They distorted the field, and were subject to rapid corrosion through electrolytic processes. When the Hoffman apparatus was used later in the program, domestic-origin, threaded Steinmann pins of appropriate diameter (4mm for the large apparatus) were substituted.”
Cheng et al., 1985	PEMF	NR/63 Prior surgical interventions included	NR	NR
Colson et al., 1988	PEMF	19/33 (57.6) nonunions treated with internal fixation	NR	19/19 “All 19 cases treated with this combined approach went on to unite within 9 months.”
Delima and Tanna, 1989	PEMF	25/29 (86.2)	Of the 25 with surgical intervention: <ul style="list-style-type: none"> • Nail/Graft: 13 • Compression Plate w/ Cancellous Graft: 7 • Nail: 7 • Plate: 1 	Nail/Graft + Nail: 16/20 (80%) united Compression Plate w/ Cancellous Graft + Plate: 6/8 (75%) united Poor fixation or infections were the main reasons for failure.

Table 3. Fixation Findings Related to Nonunion Fractures of the Long Bones and Others Treated with PEMF Non-invasive Bone Growth Stimulators (Continued)

Reference	Stimulation Type	Number of Subjects with Fixation (%)	Type of Fixation Used	Impact of Fixation on Effectiveness
Fontanesi et al., 1983	Pulsed Electromagnetic Fields (PEMF)	14/35 (40) fractures	Of the 14 with surgical intervention: <ul style="list-style-type: none"> • Plaster/Screw Fixation: 9 • Küntscher Nail: 2 • Kirschner Nail: 1 • Screw Fixation: 1 • External Fixation: 1 	“Immobilisation of the fracture is essential and must be quite firm, wheather achieved by internal or external fixation or by plaster...The main causes of failure are inadequate fixation of the fracture...”
Garland et al., 1991	PEMF	History of internal fixation: 113/193 (58.5) nonunions <i>In situ</i> internal fixation during the study: 68/193 (35.2) External fixation: 26/193 (13.5)	NR	“Variables such as the age of the patient, gender, previous attempts to achieve union (recalcitrant versus first time treatment)... did not significantly impact PEMF treatment success in this series.”
Heckman et al., 1981	PEMF	19/149 (12.8) nonunions	Of the 19 with surgical intervention w/in 3 months of electrical stimulation: <ul style="list-style-type: none"> • Plating/Grafting: 2 • Roger Anderson Device: 1 • Roger Anderson Device/Grafting: 1 • Hoffman Device: 1 • Other 14 procedures were to remove metal or necrotic bone 	17/19 (89.5%) healed Surgery occurring within 3 months of the start of electrical stimulation had a positive effect on the results. Details pertaining to which of the surgically treated healed NR

Table 3. Fixation Findings Related to Nonunion Fractures of the Long Bones and Others Treated with PEMF Non-invasive Bone Growth Stimulators (Continued)

Reference	Stimulation Type	Number of Subjects with Fixation (%)	Type of Fixation Used	Impact of Fixation on Effectiveness
Hinsenkamp et al., 1985	Pulsed Electromagnetic Fields (PEMF)	Not Reported (NR)/308 Prior surgical interventions included	NR	"It appears that the following factors have no significant effect on the success rate: 1)... 2) previous surgery before treatment, 3), 4), 5) associated surgery during treatment, and 6) implant in place during the treatment."
Madroñero et al., 1988	PEMF	10/10 (100) nonunions	Metallic plate and screws	0/4 healed with PEMF and implanted metallic plate and screws 6/6 healed with PEMF and without implanted metallic plate and screws "In our view, this can be explained because the conducting plates create a uniform bone biopotential around the fracture and thus prevent the negative polarization which stimulates callus formation."
Marcet et al., 1984	PEMF	147/147 (100) had external fixation <i>in situ</i>	NR	107/147 (72.8) united (approximately the same success rate as other methods) Failures were attributed to wide fracture gaps and insecure skeletal fixation devices.
Meskens, et al., 1990	PEMF	NR/34	NR	"The initial type of therapy appeared to have little or no effect on the success rate."
O'Connor, 1985	PEMF	16/54 (29.6) had failed internal fixation <i>in situ</i> at the start of PEMF	NR	Of the 16 patients with failed internal fixation, only 6 were evaluable at the time of analysis, of which 5 (83.3%) had proceeded to union.
Sedel et al., 1982	PEMF	0/39	Nonmagnetic	NR

Table 3. Fixation Findings Related to Nonunion Fractures of the Long Bones and Others Treated with PEMF Non-invasive Bone Growth Stimulators (Continued)

Reference	Stimulation Type	Number of Subjects with Fixation (%)	Type of Fixation Used	Impact of Fixation on Effectiveness
Sharrard et al., 1982	Pulsed Electromagnetic Fields (PEMF)	Not Reported (NR)/53 nonunions	NR	“Previous or active sepsis, the presence of plates or nails, the age of the patient or the time since the injury did not affect the results.”
Simonis et al., 1984	PEMF	15/15 (100)	Denham External Fixator	13/15 (86.7) healed

Table 4. Fixation Findings Related to Nonunion Fractures of the Foot and Hand Treated with PEMF Non-invasive Bone Growth Stimulators

Reference	Stimulation Type	Number of Subjects with Fixation (%)	Type of Fixation Used	Impact of Fixation on Effectiveness
Adams et al., 1992	Pulsed Electromagnetic Fields (PEMF)	Not reported (NR)/54 nonunions	NR	"Previous surgery does not seem to adversely affect the results of electrical stimulation."
Dhawan et al., 2004	PEMF	70/70 (100)	7.33 mm cannulated cancellous screws across Subtalar joint; 4.5 mm cannulated partially threaded cancellous screws across talonavicular joint	Adjunctive use of PEMFs [basic surgical principles for bone healing, such as adequate internal/external immobilization and bone grafting] in elective hindfoot arthrodesis may increase the rate and speed of radiographic union. Time to fusion for all PEMF groups for all bones was less than the controls.
Frykman et al., 1986	PEMF	0/50	N/A (casting only)	NR
Holmes, 1994	PEMF	0/9	N/A (all casts/no metal)	NR

Table 5. Fixation Findings Related to Non-invasive Bone Growth Stimulators for Spinal Fusion

Reference	Stimulation Type	Number of Fusions with Internal Fixation (%)	Type of Fixation Used	Impact of Fixation on Effectiveness
Bose, 2001	Pulsed Electromagnetic Fields (PEMF)	48/48 (100)	Not Reported (NR)	"Lumbar fusion with a combination of internal fixation and PEMF stimulation achieved a 97% fusion success rate and an 89% good or excellent clinical outcome in high-risk patients."
DiSilvestre and Savini, 1992	PEMF	Active: 3/31 (9.7) Placebo: NR/22	Of the 3 instrumentations: <ul style="list-style-type: none"> Louis Pedicle Screws and Plates: 2 Roy-Camille Pedicle Screws and Plates: 1 	NR 30/31 (96.7%) fused
Goodwin et al., 1999	Capacitive Coupling	142/179 (79.3) Active: 65/85 (76.5) Placebo: 67/94 (81.9)	NR	Active: 53/65 (81.5%) Placebo: 40/67 (61%)
Jenis et al., 2000	PEMF	61/61 (100)	Pedicle-screw rod instrumentation (Isola, Acromed, Cleveland, OH, U.S.A.)	No statistically significant difference in bone density or overall clinical outcome.
Marks, 2000	PEMF	11/61 (18.0) Active: 10/42 (23.8) Placebo: 1/19 (5.3)	NR	Active: 9/10 (90%) Placebo: 1/1 (100%)

Table 5. Fixation Findings Related to Non-invasive Bone Growth Stimulators for Spinal Fusion (Continued)

Reference	Stimulation Type	Number of Fusions with Internal Fixation (%)	Type of Fixation Used	Impact of Fixation on Effectiveness
Mooney, 1990	Pulsed Electromagnetic Fields (PEMF)	Active: 48/64 (75) [*] Placebo: 39/53 (73.6) [*]	Not Reported (NR)	Active: 44/48 (91.7%) Placebo: 28/39 (71.8%) “Factors such as sex, age, fusion level... and internal fixation made no difference.”
Simmons, 1985	PEMF	NR/13 Prior surgical interventions included	NR	NR
Simmons et al., 2004	PEMF	81/100 (81)	NR	54/81 (66.7%) healed “Effectiveness was not statistically significantly different for patients with risk factors such as smoking, use of allograft, absence of fixation, or multilevel fusions.”

^{*} The values in the denominators represent those subjects who demonstrated compliant device usage and not the subjects actually evaluated for the respective treatment groups (per the analysis extracted from the reference).

Table 6. Fixation Findings for Articles Discussed in Section VII of the Petition

Reference	Stimulation Type	Number of Subjects with Fixation (%)	Type of Fixation Used	Impact of Fixation on Effectiveness
Bassett, 1974	Not applicable (N/A)	N/A	N/A	N/A
Bassett, 1962	N/A	N/A	N/A	N/A
Bassett, 1975	N/A	N/A	N/A	N/A
Bassett, 1978	N/A	N/A	N/A	N/A
Bassett, 1974	N/A	N/A	N/A	N/A
Beckenbaugh, 1984	N/A	N/A	N/A	N/A
Beigler, 1994	Combined Magnetic Fields	72/116 (62.1) treated with internal fixation 33/116 (28.4) treated with external fixation	Internal fixation: Plating & intramedullary rod placement External fixation: Not Reported (NR)	NR
Boyd et al., 1961	N/A	NR/842	Of the types of bone grafting employed: <ul style="list-style-type: none"> • Nail/Graft: 9% • Onlay Graft: 63% • Phemister Graft: 6% • Dual Graft: 10% • Plate/Graft: 5% • Others: 7% 	Page 0541 of the Petition, 'Choice of procedure,' can be reviewed for relevant text.
Brighton et al., 1981	Direct Current	N/A	N/A	N/A
DeHaas et al., 1986	Pulsed Electromagnetic Fields (PEMF)	6/56 (10.7) treated with metallic internal fixation devices	NR	6/6 (100%) The presence of metal in the bone did not appear to interfere with electrical stimulation, as healing occurred in all 6 patients previously treated with internal fixation.

Table 6. Fixation Findings for Articles Discussed in Section VII of the Petition (Continued)

Reference	Stimulation Type	Number of Subjects with Fixation (%)	Type of Fixation Used	Impact of Fixation on Effectiveness
Heppenstall	Not applicable (N/A)	N/A	N/A	N/A
Mueller and Thomas, 1979	N/A	90/113 (79.6)	Of the 90 with surgical intervention: <ul style="list-style-type: none"> • Plate: 33 • Plate/Graft: 33 • Intramedullary Nail: 17 • External fixation: 4 	90/90 (100%)
Nelson et al., 2003	N/A	N/A	N/A	N/A
ZumBrunnen and Brindley, 1968	N/A	NR/140 (74.3) 145 bone grafting procedures performed on 123 of 140 ununited long bones	Of the 145 grafting procedures: <ul style="list-style-type: none"> • Cortical Onlay: 72 • Phemister: 16 • Intramedullary: 12 • Cancellous: 25 • Local: 20 	104/123 (84.6%) surgically treated bone united